Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) 01213/0203491-US0	
	Application Number 10/553,174-Conf. #1175	Filed October 13, 2006
	First Named Inventor Bruno Pasquale Franco Nardo et al.	
	Art Unit 3767	Examiner I. N. Hayman

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 47,698
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

Signature

Richard J. Katz
Typed or printed name

(212) 527-7700
Telephone number

January 22, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of 1 forms are submitted.

Docket No.: 01213/0203491-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Bruno Pasquale Franco Nardo et al.

Application No.: 10/553,174 | Confirmation No.: 1175

Filed: October 13, 2006 | Art Unit: 3767

For: DEVICE AND MACHINE FOR REGENERATING A HUMAN LIVER | Examiner: I. N. Hayman

REASONS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

January 22, 2010

Dear Sir:

In accordance with the Pre-Appeal Brief Conference Program, Applicants hereby respectfully request a pre-appeal brief panel review of the Final Office Action mailed July 24, 2009 and the Advisory Action mailed December 11, 2009 in the above-identified patent application.[1] The present Request is filed concurrent with the filing of a Notice of Appeal, payment of the appropriate fees, and before the filing of an Appeal Brief. No amendments are being filed with this request. Review is requested for the following reasons:

I. A COMBINATION OF WEITZEL AND DAVIDNER FAILS TO RENDER ANY CLAIM UNPATENTABLE

[A] Background

Claims 11, 13 and 15-17 are pending in the present application. Claims 1-10 and 18-23 have been withdrawn from consideration. Claims 11, 13 and 15-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,913,588 of Weitzel et al.

[1] Applicants' reply filed November 24, 2009 was entered by the Advisory Action.

("Weitzel") in view of U.S. Published Application No. 2002/0077581 of Davidner et al. ("Davidner").

Independent claim 11 of the present application is directed to a machine for regeneration for a human liver. Independent claim 11 recites, in part, a control device "configured to measure hematocrit and a partial pressure of molecular oxygen in the blood in extracorporeal circulation."

The Advisory Action states that

> Both Davidner [0029-0038] and Weitzel (column 9, lines 29-51) disclose a device capable of measuring the volume of blood including hematocrit.

Advisory Action, item 11.

[B] A Combination of Weitzel and Davidner Fails to Teach or Suggest a Control Device Configured to Measure Hematocrit in the Blood in Extracorporeal Circulation, as Recited in Independent Claim 11

With regard to Weitzel, in the Final Office Action the Examiner relied solely on Davidner as disclosing a control device configured to measure hematocrit. Detailed Office Action, item 4, page 3 (citing Davidner, ¶¶ 0046-0048, 0057, 0082 and 0086; Fig. 1). In the Advisory Action the Examiner now contends that both Weitzel and Davidner disclose the above-quoted feature of independent claim 11.

Weitzel describes a flow monitor 14 that measures blood flow rate in the intake and outflow lines, so that close regulation of the pump rates for intake pump 4 and outflow pump 6 can be achieved. Weitzel, column 6, lines 30-59. Further, Weitzel describes that a pressure monitor 26 measures blood pressure and/ or ultrafiltrate pressure within internal portions of the treatment device 20. Weitzel, column 6, lines 40-42. That portion of Weitzel cited in the Advisory Action, item 11, merely describes that "fluid volume losses and inputs should be

monitored." Weitzel does not describe a control device configured to measure hematocrit, nor measuring hematocrit levels at all.

Davidner, ¶¶0045-49 merely describe an oxygenator 14 and a circuit 201 that stops the function of pumps and clamps by enabling/disabling a power supply 202. Davidner, ¶¶ 0056-57 describe measuring and controlling the pressure in the superior sagittal sinus during a perfusion procedure that begins with blood flow in a retrograde direction. Davidner, ¶¶0082-83 describe sensing the pressure in the venous sinus where blood ejected from a catheter balloon 716 is delivered via a pressure lumen orifice 714. Davidner, ¶ 0086, describes determining a patient's intracranial pressure by using a pressure transducer 901 in conjunction with the electronic control circuit 201 and a data acquisition circuit 203.

That portion of Davidner cited in the Advisory Action, item 11, describes that a diluent (a plasmalyte or a saline solution) is mixed with a patient's blood. Adding the diluent results in reducing the patient's normal hematocrit level by about 50%. See, Davidner, paragraph 0029. Davidner further describes that blood flowing through a hemoconcentrator 106 increases the hematocrit level back to 100% of the patient's normal level. See, Davidner, paragraph 0033. Applicants respectfully submit that Davidner fails to disclose, or suggest, a "control device further configured to measure hematocrit . . . ," as recited in independent claim 11. Rather, Davidner merely describes diluting a patient's hematocrit level and then concentrating the blood, which results in an increase in the patient's hematocrit level. Davidner does not disclose any device measuring the hematocrit levels in the diluted, or reconcentrated, blood of the patient.

It is respectfully submitted that neither Weitzel or Davidner, singly or in combination, teaches, or suggests, a control device "configured to measure hematocrit and a partial pressure of molecular oxygen in the blood in extracorporeal circulation," as recited in independent claim 11. In contrast, Weitzel does not describe a control device configured to measure hematocrit, further, Weitzel does not even disclose, or suggest, measuring hematocrit levels at all. Davidner merely describes diluting a patient's hematocrit level and then concentrating the blood, which results in an increase in the patient's hematocrit level. However, Davidner does not disclose any device

measuring the hematocrit levels in the diluted, or reconcentrated, blood of the patient. Davidner, ¶¶ 0029, 0033.

Accordingly, a combination of Weitzel and Davidner, to the extent proper, could not render independent claim 11, or dependent claims 13 and 15-17, obvious.

CONCLUSION

For the foregoing reasons, Applicants respectfully request a review of the rejection of claims 11, 13 and 15-17, and the withdrawal of these rejections under 35 U.S.C. § 103(a).

The Commissioner is hereby authorized to charge any unpaid fees deemed required in connection with this submission, or to credit any overpayment, to Deposit Account No. 04-0100.

Dated: January 22, 2010

Respectfully submitted,

By _____

Richard J. Katz
Registration No.: 47,698
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant(s)